AngioScore®

MAY 28 2008

510(k) Summary for the AngioSculpt Scoring Balloon Catheter

1. Submitter's Name / Contact Person

Submitter:	AngioScore, Inc. 5055 Brandin Court Fremont, CA 94538
Contact Person:	Kimberley Kline Senior Regulatory Specialist Phone: 510-933-7989 Fax: 510-933-7994
Summary Preparation Date:	May 27, 2008

2. General Information

Trade Name:	AngioSculpt® PTA Scoring Balloon Catheter
Common / Usual Name:	Angioplasty catheter
Classification Name:	Percutaneous catheter
Product Codes:	DQY and LIT
Predicate Devices:	AngioSculpt® Scoring Balloon Catheter (K072225 and K080151)

3. Intended Use / Indications

The AngioSculpt PTA Scoring Balloon Catheter is intended for dilatation of lesions in the iliac, femoral, ilio-femoral, popliteal, and infra popliteal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. Not for use in the coronary or neuro-vasculature.

4. Device Description

The AngioSculpt catheter is a standard two-lumen catheter with a scoring balloon near the distal tip. The distal end of the catheter has a conventional nylon-blend balloon with a nitinol scoring element that wraps around the balloon. The scoring element creates focal concentrations of dilating force which minimizes balloon slippage and assists with luminal expansion of stenotic arteries. The balloon has radiopaque markers to aid in positioning the balloon in the stenosis, and is designed to provide an expandable segment of known diameter and length at a specific pressure.

5. Substantial Equivalence Comparison

The AngioSculpt catheter shares the same indications for use, fundamental design, scientific technology (operating principle), functional performance, and materials as the currently marketed AngioSculpt catheter. Design verification and validation testing demonstrated adequate device performance and confirmed that no new questions of safety or effectiveness for peripheral balloon angioplasty devices were raised. The changes to the subject AngioSculpt PTA Scoring Balloon Catheter do not affect the intended use of the device, alter the fundamental scientific technology of the device, or raise new issues of safety and effectiveness. The AngioSculpt PTA Scoring Balloon Catheter is therefore, substantially equivalent to the predicate AngioSculpt catheters.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 28 2008

Angioscore, Inc.
c/o Ms. Kimberley Kline
Senior Regulatory Specialist
5055 Brandin Court
Fremont, CA 94538

Re: K081220
Trade/Device Name: AngioSculpt PTA Scoring Balloon Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: DQY, LIT
Dated: April 28, 2008
Received: April 30, 2008

Dear Ms. Kline:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram Zuckerman
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

AngioScore®

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K081220

Device Name: AngioSculpt® Scoring Balloon Catheter

Indications for Use:

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Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diana R. Vaclavik

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K081220

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